

Re : Docket Number : 2004-D-0369, " Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use ; Availability"

The Washington Biotechnology Action Council is a 15-year old citizen organization which has been involved in GE policy issues on the local, state, national, and international levels.

The purpose of this submission is to object to the policies contained in the above-referenced docket, since they are a continuation of FDA's non-regulation of genetic engineering which has allowed untested material to be a part of the US food supply.

This document proposes a so-called safety assessment, which is insufficient: a company may voluntarily conduct an evaluation (or not), and consult with the FDA (or

not) as to whether its experimental GE crop material is an acceptable contaminant for the food supply (or not).

None of these factors or steps is adequate, in our view.

Although the US likes to claim that its policies are science-based, those of us who follow these issues know that from the very beginning—the 1992 decision to consider GE foods as “substantially equivalent” to conventional ones (over the protests of FDA scientists)—the motivation and practice of the FDA has been to trouble the industry as little as possible and leave consumers without protections that are the norm elsewhere in the world.

FDA Commissioner Lester Crawford apparently has described the Docket’s proposed policy as “a high priority for the Administration and the industry, to enhance public confidence, avoid product recalls, and provide an international model” for similar policies around the world.

However, a year and a half ago, the Codex Alimentarius adopted guidelines for pre-market safety assessment of foods involving modern biotechnology, and these are the international model. The US helped develop these procedures and voted to accept them (along with virtually every country in the world). The US should be consistent and follow such procedures as regards this topic of contamination of food crops by experimental GE plants. Failure to do so will just invite further foreign restrictions on the importation of foods from the US, due to foreigners’ justified fears of unhealthy contamination of US foodstuffs.

Although this “Draft Guidance” is being promoted as protecting against contamination, its own terms render it likely to allow genetically altered proteins, never approved for human consumption, to enter the food supply. We are not satisfied with a document of indeterminant legal status (it isn’t a regulation) being the government’s response to this situation. We are not satisfied with the voluntary aspect of the FDA’s GE foods program which leaves consumer health to the mercies of industry self-interest and, of course, does little to “enhance public confidence”. “Encouraging” industry to adopt a socially responsible course of action has been repeatedly shown to be inadequate for the protection of the public’s health and safety.

The lack of transparency in existing US practices (as well as in the proposed Docket) is also inconsistent with evolving international norms, as expressed both in the Codex and the Cartagena Biosafety Protocol. It is logically impossible to determine an “acceptable” level of contamination when the vital information is hidden from the public. It is not clear how the FDA will define and utilize this concept; what basis will be employed? “Acceptability” to regulators is not sufficient; there must be acceptability to the general public. Regulators have been known in the past to be too deferential to industry’s economic considerations in adopting procedures subsequently changed because of public vigilance, often after considerable damage. Lack of transparency means that testing is rendered infeasible, thus undercutting the frequent claims by the US in international fora that US oversight of GE foods is based on science.

Industry claims of “confidential business information” have been allowed to run amok, currently covering almost half of the genes being experimentally tested in fields, and consumer health and safety are thereby relegated to secondary considerations. This pattern cannot continue. In a recent poll by the Pew Initiative for Food and Biotechnology (certainly no mindless critic of the technology), some 85% of US consumers strongly believe that the government should assure the safety of GE foods before they are marketed—perhaps by following the Codex international norms, we would suggest. For example, the burden of proof of safety, as with other food additives, should be on the industry proponents, not on regulators nor hapless consumers.

Undoubtedly, the irresponsibility on the part of the US government, represented by this “guidance document,” will be used by the European Commission as a further

defense to the charges filed against it by the US in the WTO regarding European precautions on GE crops and foods.

The US used to employ precautionary regulation; scholars have identified approximately 40 such statutes still on the books (from the era before 1980, when consumer health was valued more than increased corporate profits). We insist that the pendulum has swung too far, and that avoiding health and ecological damage from GE contamination needs to be more highly valued by FDA officials.

Although the industry hopes this FDA document will shield it from legal liability, the NGO community, farmers' organizations, and consumer groups will do all we can to assure that those responsible for recklessly causing harm via the dissemination of GE material are held to account. While formal regulations (which have undergone the full process of the Administrative Procedures Act, etc), have been held to limit liability, we will argue that this Docket is not a regulation but a corporate fig leaf that will not shield corporate conduct that is heedless of the public's well-being.

We therefore urge the FDA to withdraw this document and initiate formal regulatory procedures which require the conducting of scientific safety assessments of GE foods and food contaminants, along the lines of the Codex provisions, in order to be truly protective of consumer health.

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